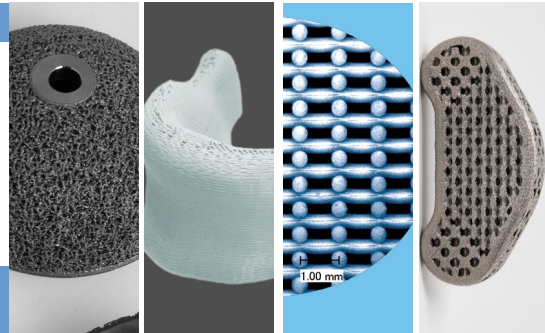




# Building Evidence for 3D Printing Applications in Medicine

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Advances in medical technology have spurred an evolution towards personalized medicine for improved healthcare delivery and patient outcomes. Three-dimensional (3D) printing, also referred to as additive manufacturing, has become an important contributor to this evolution and remains an essential technology in our healthcare system of the future. While surgical uses of 3D printing-centric therapies have a long history beginning with anatomical models for bony reconstruction planning,<sup>1</sup> widespread use has been limited. Primary challenges impacting patient access to the benefits of 3D printing include insufficient evidence of patient outcomes and cost-effectiveness, both of which will need to be expanded to set appropriateness guidelines that will lead to standards of care and reimbursement.

In May 2016, medical 3D printing stakeholders including device manufacturers, researchers,

point-of-care manufacturers, technology developers, regulatory representatives, and clinicians, gathered to discuss and address the need to bolster scientific evidence for 3D printing. (Appendix) The combined experience of these stakeholders is critical to the safety and efficacy of 3D printing applications. Their knowledge can provide information needed for patients and clinicians as well as vital information for healthcare policy makers and payors to make well-balanced health policy decisions. The meeting, Building Evidence for 3D Printed Applications in Medicine, took place in Orlando, Florida co-located with SME’s annual RAPID event. Focusing on anatomical models, patient-matched surgical planning and surgical guides, and patient-matched implants, presentations and discussion addressed the clinical, engineering, and economic perspectives.

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## BACKGROUND

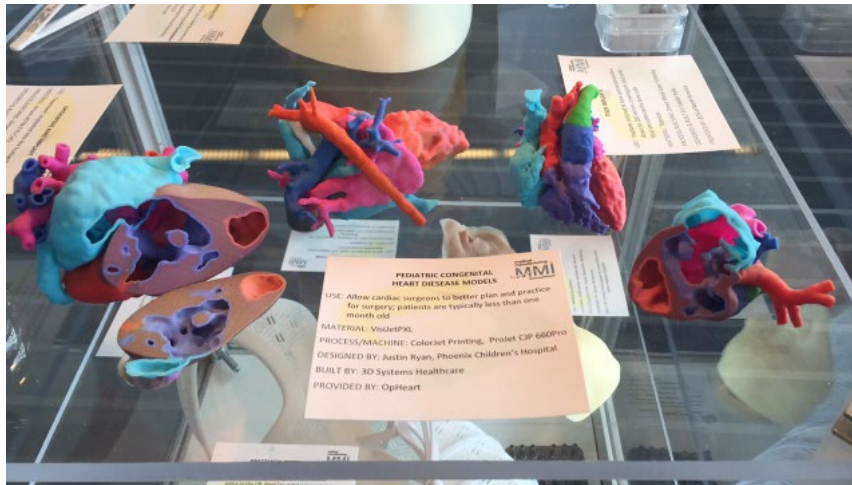
In evidence-based medicine, the PICO model (Population, Intervention, Comparison, Outcome) is generally used to frame and answer clinical research questions<sup>2</sup> and is a starting point for health economic assessments.<sup>3</sup> It is a useful tool to properly define what is needed to assess the clinical and economic value of 3D printing in healthcare. The quality and strength of evidence is defined based on the study design and research methods, as illustrated by the different levels of evidence in the Oxford Model.<sup>4</sup> Randomized clinical trials with large sample sizes or systematic reviews are preferred, but difficult to achieve for rare diseases or for devices that are used for different applications.<sup>5</sup> In orthopedic applications for example, several systematic reviews mention insufficient statistical power, lack of homogeneity and a high risk of bias in published studies as a major limitations to the current evidence for 3D printing in the scientific literature.<sup>6,7,8</sup> Besides limitations related to study population and study design, the fact that the sample size of a clinical trial is directly proportional to the cost, can be a burden for small and mid-size companies. 3D printing is used or studied for a variety of medical uses, encompassing low volume

to high volume procedures, Class I to Class III devices, and numerous types of materials. Some devices are patient-matched while others are off-the-shelf components. The medical field still needs to develop better assessment methods and tools for adequate evaluation of this technology. Hence, the consideration of desired versus feasible levels of evidence should be made to define the appropriate level that is required for different 3D printed applications. Besides evidence on patient outcomes and safety, the most important factors that determine effectiveness and costs should be determined.<sup>9</sup> In the context of reimbursement, it is important to weigh the risks and benefits for a specific treatment, test or procedure within available resources for a specific population. Based on this information, a framework for building evidence for effectiveness, appropriateness and feasibility of 3D printed medical applications can be established. Without clear guidelines on how economic studies and clinical trials should be designed and conducted, and without a clear assessment of endpoints that need to be investigated, there is risk of inappropriate use and misallocation of limited resources for medical 3D printing.

## METHODS

To address priorities for population, comparators, outcomes, assessment methods, study design and overall priorities, participants in the May 2016 program were divided into groups with

representatives of each stakeholder group represented in the discussion. The results of group discussion were then shared to identify commonalities.



*Pediatric cardiac models produced for Phoenix Children's Hospital*

## RESULTS (Areas Of Discussion/Review)

### Anatomical models

For cardiovascular treatments and more, 3D printing is promising for patient-tailored practice, but can also improve the education of physicians and patients. 3D-printed anatomical models can make surgeons better prepared to perform surgery, and better preparation results in improved surgical outcomes. For orthopedic and craniomaxillofacial surgery, the detailed visualization of a patient's bone defect or anatomical malformation is of high value in the preparation and execution of surgery. The model gives not only visual information, but also tactile feedback to the surgeon. With the length of time and experience level, discussion of anatomical models resulted in the following list of indicators and priorities.

*Population:* Group consensus for anatomical models indicated a priority to adapt existing or develop new tools for anatomical models. This should include indicators when use of anatomical models will add value to 3D images. An example of this could be supporting decision-making for the use of allografts. Additional priorities included methods to increase the speed with which a model is created and to address risk factors for required imaging levels for high quality images for detailed models. Several areas were identified for appropriate and increased use of anatomical models.

- **Bone:** 3D printed models can support treatment planning for trauma (at all ages), reconstruction (particularly for elderly patients), long and flat bone issues, and spinal concerns.
- **Tumors:** A variety of tumor treatments can be supported with the use of anatomical models including those in the kidney, pancreas, spleen, lung, liver, brain, prostate, esophagus, gallbladder, and diaphragm. Of these, kidneys may be a priority for expanded study due to the large population, clear pathology categories, well-defined patient-specific variables, and common clinical follow-up data. Some studies have already begun.<sup>1</sup>
- **Neurovascular:** 3D printed models can and have been used to understand aneurysms as well as to create tests for placement of stents.<sup>2</sup>

*Comparators:* Although consensus was not reached on the priorities for comparators, those identified included raw medical imaging data, 3D computer visualization (volume rendering), and intraoperative imaging. Virtual and augmented reality were identified as possible future comparators. Specific comparators for three areas were also identified.

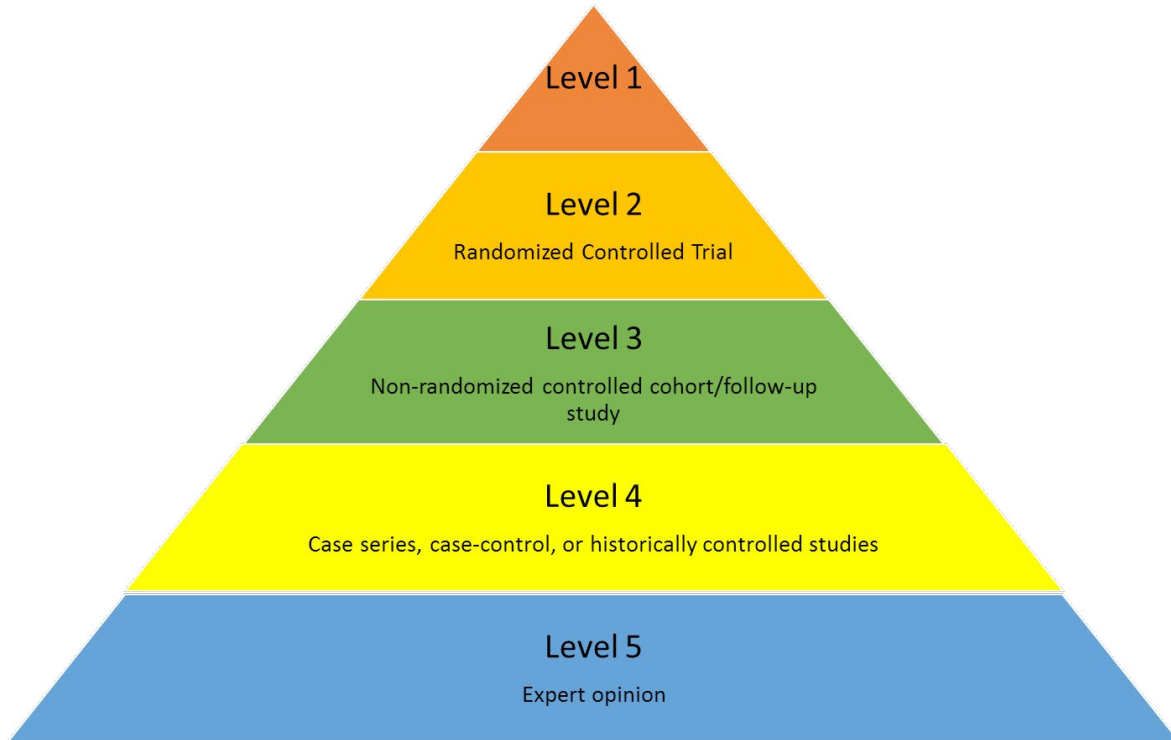
- **Kidney:** CT scan with or without contrast to create protocol, nephrometry score, location of lesion/vital structures, size of lesion, measurements, and possibly 3D rendering.
- **Lung (Pancoast Tumor):** PET scan and/or PET/CT scan to create protocol, measurements, and if CTA, volume render.
- **Primary (Brain Tumor):** MRI, size, location, shape, enhancement, perfusion, intraoperative imaging, and stealth MRI, how much is resected.

*Outcomes:* Reviewing three separate areas (kidney, Pancoast tumor, and brain), the groups agreed that in-patient hospital time is a key outcome indicator to demonstrate effective use of anatomical models. Two (kidney, brain) also identified blood loss and surgeon time as priority outcome metrics. Additional indicators are listed below with the priority measurements in italics.

- **Kidney:** hospital time, kidney preservation (reserved volume), function (revival, 24-hour creatinine clearance, cold perfusion time, surgeon time, patient understanding and consent, and blood loss
- **Pancoast Lung:** in-patient hospital time, negative margins, neurologic function (brachial plexus), pulmonary function, invasiveness of surgery, position of patient on table, surgical time, and blood loss
- **Brain:** in-patient hospital time, function, surgeon time, anatomic understanding, and blood loss

*Assessment Methods:* The discussion groups identified several measurements; some objective and others subjective. All of which complement the identified outcomes measurements. These include complication/revision rates, patient reported outcomes (pre and post), ischemia time, aesthetics scale, surgeon confidence, return to functionality as assessed by physician, discharge time, and infection rates. Additionally, several non-outcome indicators were identified including studies, papers, guidelines, and survey of anatomical models.

*Study Design:* Anatomical models can be evaluated through studies with variable levels of evidence (1 to 5). Challenges for studies include using design models designed for large volumes of patients in an area that has a relatively low volume. The groups were asked to identify the priority and realistic highest level of evidence achievable.



### *Systematic Review of Randomized Controlled Trials*

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While opinions differed, the largest number of participants indicated that level 3, comparative studies may be the highest achievable level based on current practice. To support further studies, several suggestions were made including consistent protocols and the developing multiple institution studies.

*Priorities:* In final evaluation for anatomical models, each group identified priorities to impact more patients. All groups identified outcomes as one of the top two priorities. Population was also identified as a high priority by most groups. All groups rate study design as a lower priority.



*Surgical guide for correction of forearm malunion shown on anatomical models of forearm bones; produced by Materialise.*

## PATIENT-MATCHED SURGICAL GUIDES

Patient-matched surgical guides are designed for a unique fit to the patient's bone in order to guide the surgical tools to reproduce a preoperative plan. The intention of this application is to improve the outcome of the surgery or make surgery more efficient; implant placement; these devices offer an alternative for current implantation techniques using conventional generic instrumentation, navigation or robotic assisted implant placement. Today, patient-matched surgical guides are increasingly being used in surgical domains such as orthopedic, craniomaxillofacial and spinal surgery. Preoperative planning and guides can improve the (time-) efficiency, accuracy and consistency of a surgical procedure and consequently lead to more predictable outcomes, especially for interventions of high complexity.<sup>14,15</sup> To focus discussion, groups addressed different areas of use: corrective osteotomies, craniomaxillofacial, and joint replacements.

*Population:* Identified corrective osteotomies population, include multi- planar reconstruction, double bone, scoliosis, long bone, congenital defects, and dwarfism. Craniomaxillofacial populations identified in order of frequency were dental implants, orthognathic, fibula free flap for mandible/maxilla reconstruction, craniofacial reconstruction, and trauma.

*Comparators:* All areas include freehand surgery as a comparator. For joint replacements, comparators included conventional instruments, robotics, sensors for knee balancing, and other standard reference to other techniques. Today's standard for corrective osteotomies include CT and MRI, and tracing paper. Craniomaxillofacial comparators include CT scans and 3D renderings. Regardless of comparators used, the groups agreed on important factors:

- Address 3D problems in 3D digital environment.
- When comparing two guiding systems, all study arms should use the same endpoints, assessed with the same methods.
- The planning tool and the guides should be evaluated concurrently.
- Focus on guide performance in terms of accuracy, rather than the planning.

*Outcomes:* Many outcome indicators for the use of surgical guides are similar to those for anatomical models.

- **Joint replacement** outcomes included operating room efficiency, accuracy from plan to surgery, functional scores, patient satisfaction, rehab time, and infection rates. Additional considerations included the importance of American Academy of Orthopaedic Surgeons guidelines, and avoidance of 90-day complaints.
- **Corrective osteotomies** was divided into two areas focusing on the quality of life with reoperation, operation time applying to both. For oncology, additional outcomes included functionality as secondary, infection, recurrence, functionality, and tess and msts scores. For non-oncology, outcomes included a higher priority for functionality, fluoroscopy time, cost, and surgeon confidence.
- **Craniomaxillofacial** outcomes included surgeon time including preoperative, functionality, and aesthetics with a priority on functional scores, operating room efficiency, and accuracy.

*Assessment Methods:* Again, some assessment methods for surgical guides are similar to those for anatomical models including reduced surgery time, infection rates, and readmissions. A need for new integrated metrics was identified, combining cost with all other parameters. Priority was set on validating the link between accurate assessment methods (e.g. navigation) and clinical methods (e.g. CT Perth protocol or radiographs) as well as developing and validating 3D assessment methods.

*Study Design:* For prevalent joint replacement pathologies, the group identified level 1, meta-analysis based on randomized clinical trials as appropriate. For craniomaxillofacial, while randomized clinical trials may be possible, comparative studies are appropriate.

*Priorities:* For patient-matched surgical guides, similar to anatomical models, higher priority was given to outcomes while study design was assigned a lower priority.



Overall, the evidence for the use of patient-matched implants may be the most difficult based on the individual nature of each implant. While patient-matched devices create opportunities for development for rare diseases like the tracheal splint developed to treat tracheobronchomalacia, this uniqueness proves to be challenging when attempting to function within a regulatory framework designed for traditionally manufactured implants. Together with the increased popularity and use of 3D printing in medicine, first initiatives have been taken to set up guidelines to regulate the market of 3D printed medical devices. One example is the FDA Additive Manufacturing Working Group.<sup>17</sup>

Easy customization in 3D printed parts is an inherent property of this technology and allows for mass customization of surgical instruments and tools that fit to each patients' unique anatomy. 3D printing also has unique potential to facilitate novel, protean treatment for rare disorders that have historically been neglected by medical device development. The absence of large case series calls for a flexible framework for building evidence that should take into account some key variables such as rarity of the disorder being treated, surgical volume, and indications to facilitate patients with complex and rare pathologies access to innovated 3D-printed solutions while also ensuring safety and quality for all patients.

## CONCLUSIONS

“Building Evidence for 3D Printed Applications in Medicine” called for an urgent need for new guidelines for evidence to prove that 3D printed devices are ensuring good patient care at a reasonable cost. First ideas to work towards guideline documents that may drive clinical research, clinical practice, and reimbursement were discussed. Specific efforts identified included:

- **Appropriateness guidelines:** Particularly for anatomical models, published studies already available may allow for development of reliable appropriateness guidelines. Within the clinical setting, much of this is done within radiology, making the Radiological Society of North America a likely candidate to create recommendations. For surgical guides, joint replacement may be an area ready for development of appropriateness guidelines. The American Academy of Orthopaedic Surgeons is a likely candidate for this.
- **Index/registry:** To support gathering of case studies, the National Institute of Health 3D Print Exchange has been suggested as a possible platform to build an international index or registry of models and use cases.

Continuation of this industry-wide initiative with all stakeholders involved (associations of clinicians, health policy makers, manufacturers, clinical researchers and academia) is necessary to work on a common set of guidelines to generate evidence that support further growth of this new and promising technology.

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## APPENDIX A

### VIDEOS

- Overview:  
[youtube.com/watch?v=ae8t8HKlxEc&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft](https://youtube.com/watch?v=ae8t8HKlxEc&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft)
- May 2016 Opening Remarks:  
[youtube.com/watch?v=DOZymt-N5b8&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=12](https://youtube.com/watch?v=DOZymt-N5b8&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=12)
- Anatomical Models
  - CLINICAL: [www.youtube.com/watch?v=LqA86iWIRrs&index=16&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft](https://www.youtube.com/watch?v=LqA86iWIRrs&index=16&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft)
  - ENGINEERING: [youtube.com/watch?v=XAvVcOzBqGI&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=17](https://youtube.com/watch?v=XAvVcOzBqGI&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=17)
  - ECONOMIC: [youtube.com/watch?v=oak5sa7EJT8&index=14&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft](https://youtube.com/watch?v=oak5sa7EJT8&index=14&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft)
- Surgical Guides/Instruments
  - CLINICAL: [youtube.com/watch?v=gXE4\\_\\_SCgRc&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=18](https://youtube.com/watch?v=gXE4__SCgRc&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=18)
  - ENGINEERING:  
[youtube.com/watch?v=91yqF3GQ2Oo&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=19](https://youtube.com/watch?v=91yqF3GQ2Oo&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=19)
  - ECONOMIC:  
[youtube.com/watch?v=ImF3ykXNDN8&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=20](https://youtube.com/watch?v=ImF3ykXNDN8&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=20)
- Patient-matched Implants
  - CLINICAL: [youtube.com/watch?v=H4PguihRhGs&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=23](https://youtube.com/watch?v=H4PguihRhGs&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=23)
  - ENGINEERING:  
[youtube.com/watch?v=NqVbWLTxICM&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=21](https://youtube.com/watch?v=NqVbWLTxICM&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=21)
  - ECONOMIC: [youtube.com/watch?v=XLNXSFIMu\\_c&list=PLR6N8258i6Xo-ezn-QEO7w\\_yFVs2n6cft&index=22](https://youtube.com/watch?v=XLNXSFIMu_c&list=PLR6N8258i6Xo-ezn-QEO7w_yFVs2n6cft&index=22)

## APPENDIX B

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